Docket No. 5/1275

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Gerald Juergen Roth et al.	Group Art Unit: 1624	
Serial No.:	09/678,682	Examiner: Hong Liu	
Filed:	Oct. 3, 2000	Confirmation No.: 6798	
Patent No.:	6,762,180		
For:	Substituted Indolines Which Inhibit Receptor Tyrosine Kinases		

PETITION UNDER 37 C.F.R. § 1.183

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Petitioners hereby request that the Director suspend the rules and consider their Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment ("PTA") submitted herewith.

FACTS

U.S. Patent No. 6,762,180 (the "'180 patent") issued on July 13, 2004. The PTA calculated by the USPTO at the time of the '180 patent's issuance is 68 days. That calculation was made applying the methodology set forth in a notice entitled "Revision of Patent Term Extension and Patent Term Adjustment Provisions," 69 Fed. Reg. 21704 at 21706 (Apr. 24, 2004) ("2004 Notice").

The regulations set forth in the 2004 Notice were intended to implement 35 U.S.C. §154(b), which makes certain "guarantees" regarding the prompt examination and issuance of

patent applications and requires that applicants be compensated for the delays experienced when those guarantees are not met. The delays relevant to this Petition are listed in subparagraphs (A) and (B) of § 154(b)(2) and are referred to as "A Delay" and "B Delay."

The USPTO's regulations failed to compensate patent applicants for both A Delay and B Delay, instead only adjusting patent term by the larger of the two delays. These flawed regulations ignored Congress's mandate that patent applicants should not bear the cost of the USPTO's failure to meet each of the separate guarantees set forth in Section 154(b). Because the USPTO failed to account for each of those guarantees, patentees were denied the full number of compensating days of patent term to which they were entitled.

Wyeth v. Dudas, 80 F. Supp. 2d 138 (D.D.C. 2008) ("*Wyeth* District Court Decision") held that the USPTO's procedures were contrary to the plain language of Section 154(b) — a decision that was affirmed on appeal in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) ("*Wyeth* CAFC Decision"). However, it was not until after the *Wyeth* CAFC Decision that the USPTO finally accepted that its PTA policy failed to comply with Section 154(b) and promulgated an Interim Procedure[1] for recalculating PTAs under the correct interpretation of the statute.

The USPTO's Interim Procedure for correcting erroneously calculated PTAs, however, was available only for those patents that fortuitously issued during the 180 days prior to the announcement of the Interim Procedure in the Federal Register on February 1, 2010 (the "*Wyeth* look-back period"). Thus, if a patent happened to issue within 180 days before February 1, 2010,

[1] "Interim Procedure for Patentees To Request a Recalculation of the Patent Term Adjustment To Comply With the Federal Circuit Decision in *Wyeth v. Kappos* Regarding the Overlapping Delay Provision of 35 U.S.C. 154(b)(2)(A)" 75 Fed. Reg. 5043 (Feb. 1, 2010) [*hereinafter* Interim Procedure].

its owner could have its term corrected; but owners of patents that happened to issue before the 180-day cutoff were left with no remedy and deprived of the full statutory term that Congress had guaranteed. This is the problem faced by Petitioners, whose '180 patent issued over five years before the *Wyeth* look-back period.

Accordingly, Petitioners request that the Director suspend the rules governing the timing of requests for reconsideration of PTAs and accept for consideration the accompanying Petition Under 37 C.F.R. § 1.705(d) and Request for Reconsideration of Patent Term Adjustment.

STATUTES AND RULES RELEVANT TO THIS PETITION

The time for filing requests for reconsideration of PTAs is set forth in 37 C.F.R. § 1.705(d) and (e):

> (d) If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, *any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued*. . . . (emphasis added).
>
> (e) The periods set forth in this section are not extendable.

However, 37 C.F.R. § 1.183 allows the USPTO to waive filing deadlines, such as those of Rules 705(d) and (e), when justice requires:

> In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed.

As Rule 183 makes clear, the USPTO does not have authority to waive any regulation that is "a requirement of the statutes." The only statutory provision concerning the time for seeking review of a PTA calculation is 35 U.S.C. §154(b)(4), which provides:

> (4) Appeal of patent term adjustment determination. –
>
> (A) An applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration.[2]

This statute presents no obstacle to the request being made in the accompanying Petition Under Rule 705(d). Rather, it simply provides that if the Petition were to be denied, and a subsequent request for reconsideration were denied as well, then Petitioners would have 180 days from the denial of their request for reconsideration to file a district court action challenging the denial of the Petition. Further, another section of the patent statutes, 35 U.S.C. §254, provides that errors such as the PTA miscalculations at issue here, which are clearly disclosed in the USPTO's files, may be corrected at any time:

> Whenever a mistake in a patent, incurred through the fault of the Patent and Trademark Office, is clearly disclosed by the records of the Office, the Director may issue a certificate of correction stating the fact and nature of such mistake, under seal, without charge, to be recorded in the records of patents. . . .

REMARKS

I. The USPTO's Systematic Misapplication of Section 154(b) Has Placed Petitioners in an "Extraordinary Situation" Justifying Relief Under Rule 183

As shown in the accompanying Petition Under 37 C.F.R. §1.705(d), it is indisputable that the USPTO miscalculated the PTA for the '180 patent under its erroneous pre-*Wyeth* regulations.

[2] The quoted text of §154(b)(4)(A) went into effect on January 14, 2013. *See* section II.B., below.

Petitioners relied on those regulations when it did not challenge that calculation within the 2-month deadline of Rule 705(d). In light of the unequivocal statements made in the 2004 Notice regarding §154(b), Petitioners' reliance on the USPTO's statutory interpretation was reasonable. *See, e.g., Quest Commc'ns. Int'l. v. FCC*, 229 F.3d 1172, 1183-84 (D.C. Cir. 2000) (such notices, along with agency policies and procedures, constitute "binding rules of substantive law" that may be relied upon.)

The USPTO did not acknowledge its own error in its PTA calculation methodology until 2010 – over five years after the '180 patent issued. By that time, Petitioners could not satisfy Rule 705(d)'s requirement that requests for correction of PTAs be filed within two months of the patent's issuance. Nor could they make use of the Interim Procedure that waived the two-month limit for patents that happened to issue no more than 180 days before February 1, 2010. Thus, Petitioners have been deprived of their statutorily guaranteed patent term, but are left with no remedy under the USPTO's regulations.

This is precisely the type of "extraordinary situation" that Rule 183 was designed to mitigate. Indeed, if the unlawful deprivation of patent term as a result of a statutory interpretation that two courts have ruled to be wrong is not an "extraordinary situation for which justice requires waiver," it is hard to imagine what is. The USPTO has already acknowledged the extraordinarily unjust effect of its misapplication of §154(b) by waiving the two-month time limit for a swath of patentees in the Interim Procedure. There is no plausible reason to deny Petitioners the same relief merely because their patent happened to issue more than 180 days before the Interim Procedure's arbitrary *Wyeth* look-back date.

II. The Patent Statute Imposes No Deadline for and Grants Authority to the USPTO to Correct Its Own Errors in PTA Calculations

A. 35 U.S.C. § 254 Grants the USPTO Authority To Correct Its Own Errors in PTA Calculations at Any Time

The patent statute does not preclude the USPTO from correcting its erroneous PTA calculation in this case and, in fact, grants the USPTO the authority to do so. 35 U.S.C. § 254 provides that "*[w]henever* a mistake in a patent, incurred through the fault of [the USPTO], is clearly disclosed by the records of the office, the Director may issue a certificate of correction stating the fact and nature of the mistake. . . ." (emphasis added). It is indisputable that the error in PTA calculation at issue here is "clearly disclosed" in the USPTO files. Accordingly, the statute allows the USPTO to correct its own erroneous calculation at any time. The only restriction on requests for PTA correction is the two-month limit of 37 C.F.R. § 1.705(d), a regulation that indisputably can be waived pursuant to § 1.183, and, which the USPTO actually did waive in the Interim Procedure for a subclass of patentees.

B. 35 U.S.C. §154(b)(4)(A) Places no Restriction on the USPTO's Authority to Correct Its Own Errors in PTA Calculations

As noted previously, the only statute providing a deadline for PTA reviews is 35 U.S.C. §154(b)(4)(A), which provides:

> (A) An applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration.

This version of §154(b)(4)(A) was enacted into law on January 14, 2013, and "shall apply to proceedings commenced on or after such date of enactment." An Act to Correct and Improve

Certain Provision of the Leahy-Smith America Invents Act and Title 35, United States Code § n (Effective Date).[3]

By its plain terms, §154(b)(4)(A) places no restriction on the USPTO's authority to correct its own erroneous PTA determinations and a patentee's right to request such corrections. Rather, it simply limits the time for filing a civil action in district court after a request for a PTA correction has been denied. As such, it would govern the timing of a district court action by Petitioners if their Petition under 37 C.F.R. §1.705(d) and a subsequent request for reconsideration were denied, but has no effect on the USPTO's authority to consider and grant the Petition.

[3] The pre-January 14, 2013, version of this statute required district court challenges to certain PTA decisions, i.e., those transmitted with the notice of allowance, to be filed within 180 days of the patent's issuance. Even if this Petition had been filed when the old version of §154(b)(4)(A) was in effect, the statute would have presented no obstacle to the relief sought because the PTA determination at issue here is the final PTA determination made at the time of issuance, not the determination made under the former §154(b)(3), which was transmitted with the notice of allowance.

CONCLUSION

For the foregoing reasons, Petitioners respectfully submit that the Request for Suspension of the Rules should be GRANTED and that the Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment submitted herewith should be entered and favorably reviewed. Early notification of such action is earnestly solicited.

Dated: April 8, 2013

Respectfully submitted,

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